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## ANTI-TATAR ORAL CARE COMPOSITIONS PROVIDING CRYSTALLISATION PREVENTION

## TECHNICAL FIELD

The present invention relates to mouthwash or mouthrinse oral care compositions, with anti-tartar and anti-calculus effects, wherein said oral compositions comprise pyrophosphates as active agents. In addition, said oral compositions are stable against crystal formation in solution even if the product was frozen and thawed up again.

## BACKGROUND OF THE INVENTION

Oral care products such as dentifrice and mouthwash are routinely used by consumers as part of their oral care hygiene regimens. It is well known that oral care products can provide both therapeutic and cosmetic hygiene benefits to consumers. Therapeutic benefits include caries prevention 20 which is typically delivered through the use of various fluoride salts; gingivitis prevention by the use of an antimicrobial agent such as triclosan, stannous fluoride, or essential oils; or hypersensitivity control through the use of ingredients such as strontium chloride or potassium nitrate. 25 Cosmetic benefits provided by oral care products include the control of plaque and calculus formation, removal and prevention of tooth stain, tooth whitening, breath freshening, and overall improvements in mouth feel impression which can be broadly characterized as mouth feel aesthetics. Calculus and plaque along with behavioral and environmental factors lead to formation of dental stains, significantly affecting the aesthetic appearance of teeth. Behavioral and environmental factors that contribute to teeth staining propensity include regular use of coffee, tea, cola or tobacco 35 products, and also the use of certain oral products containing ingredients that promote staining, such as chlorhexidine and

While the art has addressed some of the formulation issues of oral care products relating to cosmetic benefits, 40 there continues to be a need in stain prevention and anticalculus formation from products for daily use such as dentifrice and mouthwash. The tooth structures that are generally responsible for presenting a stained appearance are enamel, dentin, and the acquired pellicle. Extrinsic staining of the acquired pellicle can arise as a result of compounds, such as tannins and other polyphenolic compounds that have become trapped in and tightly bound to the proteinaceous layer on the surface of the teeth. Discoloration from this type of staining can usually be removed by mechanical methods 50 of tooth cleaning.

In contrast, intrinsic staining occurs when the staining compounds penetrate the enamel and even the dentin, or alternatively, such staining arises from sources within the tooth. Discoloration from intrinsic staining is not readily 55 amenable to mechanical methods of tooth cleaning. Chemical methods, which utilize substances that can penetrate into the tooth structure, are usually required to eliminate such discoloration. Thus, for oral care products for daily use such as dentifrice and mouthwash to provide overall cleaning, it 60 is necessary to add ingredients for provision of antiplaque and anticalculus benefits as well as stain removal and stain control. Such ingredients for removal and control of stain and calculus include abrasives for mechanical cleaning and bleaches, surfactants and chemical chelants for chemical 65 cleaning. Dental abrasives provide important whitening benefits, particularly on 'brushed' areas of teeth, but unfortu2

nately are of limited effect in controlling aesthetically undesirable stains that form along the gumline and interproximally. The stain is mechanically abraded through the use of abrasives or polishing agents normally employed in toothpaste preparations. Bleaches such as urea peroxide, hydrogen peroxide or calcium peroxide, represent the most common forms of whitening agents for teeth. It is believed that peroxides whiten teeth by releasing hydroxyl radicals capable of breaking down the plaque/stain complex into a form that can be flushed away or removed by an abrasive. However, bleaches added to dentifrice and mouthwash, are typically present in low concentrations due to stability and safety limits unique to these product types. At these low concentrations, bleaches which are oxidizing agents have not generally been effective at tooth whitening and stain control. Bleaches and abrasives do not functionally act to prevent acquisition of stains. Abrasive use can reduce rates of stain acquisition by daily removal of newly acquired stains, but this action is a 'treatment' for existing stain, not a preventive chemical action.

Chelants have been suggested in the art for the purpose of retarding calculus formation and removing calculus after it is formed. The chemical approach to calculus inhibition generally involves chelation of calcium ion and/or crystal growth inhibition which prevents the calculus from forming and/or breaks down mature calculus by removing calcium. In addition, chemical chelants can in principle remove stains by binding to teeth surfaces thereby displacing color bodies or chromagens that cause staining. The retention of these chelants can also prevent stains from accruing due to disruption of binding sites of color bodies on tooth surfaces. A number of agents with chelating properties for use in controlling plaque, calculus and stain have been disclosed in the art. For example, ethylenediaminetetraacetic acid, nitrilotriacetic acid and related compounds are disclosed in British Patent 490,384, Feb. 15, 1937; polyphosphonates in U.S. Pat. No. 3,678,154, Jul. 18, 1972 to Widder et al., U.S. Pat. No. 5,338,537 issued Aug. 16, 1994 to White, Jr., and U.S. Pat. No. 5,451,401 issued Sep. 19, 1995 to Zerby et al.; carbonyl diphosphonates in U.S. Pat. No. 3,737,533, Jun. 5, 1973 to Francis; a zinc-polymer combination formed by the reaction or interaction of a zinc compound with an anionic polymer containing carboxylic, sulfonic and/or phosphonic acid radicals in U.S. Pat. No. 4,138,477, issued Feb. 6, 1979, to Gaffar; tartaric acid in U.S. Pat. No. 5,849,271 issued Dec. 15, 1998 and U.S. Pat. No. 5,622,689 issued Apr. 22, 1997 both to Lukacovic; acid or salt form of tartrate monosuccinate, tartrate disuccinate, and mixtures thereof in U.S. Pat. No. 5,015,467 issued May 14, 1991 to Smitherman; acrylic acid polymer or copolymer in U.S. Pat. No. 4,847, 070, Jul. 11, 1989 to Pyrz et al. and in U.S. Pat. No. 4,661,341, Apr. 28, 1987 to Benedict et al.; sodium alginate in U.S. Pat. No. 4,775,525, issued Oct. 4, 1988, to Pera; polyvinyl pyrrolidone in GB 741,315 published Nov. 30, 1955, WO 99112517 published Mar. 18, 1999 and U.S. Pat. No. 5,538,714 issued Jul. 23, 1996 to Pink et al.; and copolymers of vinyl pyrrolidone with carboxylates in U.S. Pat. No. 5,670,138 issued Sep. 23, 1997 to Venema et al. and in JP Publication No. 2000-0633250 to Lion Corporation, published Feb. 29, 2000.

Dentrifrices and mouthwashes containing soluble pyrophosphate salts have also been disclosed in the art, the pyrophosphates being indicated for a variety of purposes including as anticalculus agent. Included among such disclosures are U.S. Pat. No. 2,941,926, Jun. 21, 1960 to Salzmann et al.; U.S. Pat. Nos. 3,927,201 and 3,927,202, Dec. 16, 1975 to Baines et al. and Harvey et al., respectively;